

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DIETRICH, et al.

Serial No.: 09/980492

Art Unit: 1615

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Examiner: SHEIKH, H.

For: **NOVEL PREPARATION AND ADMINISTRATION FORM COMPRISING AN  
ACID-LABILE ACTIVE COMPOUND**

Appendix A

Please amend the claims according to the following "marked-up"  
copy of the claims:

1. (Amended) An administration form for acid-labile active compounds, comprising pharmaceutical excipients and multiple individual active compound units, wherein the acid-labile active compound is selected from the group consisting of an acid-labile active proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in the individual active compound units in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin.
9. (Amended) The administration form as claimed in claim 6,

wherein the basic compounds are inorganic basic salts, amines or fatty amines [such as ammonium carbonate and sodium carbonate, amines such as meglumine, di- or triethylamine and TRIS (2-amino-2-hydroxymethyl-1,3-propandiol) or fatty amines such as stearylamine].

11. (Amended) An active compound unit comprising an acid-labile active compound, wherein the acid-labile active compound in the active compound unit is selected from the group consisting of an acid-labile active proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin.

Please add the following new claims:

21. (New) The administration form as claimed in claim 1, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, pantoprazole, lansoprazole and rabeprazole.

22. (New) The administration form as claimed in claim 1,

wherein the proton pump inhibitor is pantoprazole sodium sesquihydrate, (-)-pantoprazole sodium sesquihydrate, omeprazole magnesium, omeprazole, esomeprazole magnesium or esomeprazole.

23. (New) The administration form as claimed in claim 1, wherein the proton pump inhibitor is pure enantiomer.

24. (New) The administration form as claimed in claim 1, wherein the proton pump inhibitor is esomeprazole or (-)-pantoprazole.

25. (New) The administration form as claimed in claim 3, wherein the microspheres have a particle size range of 50-500  $\mu\text{m}$ .

26. (New) The administration form as claimed in claim 3, wherein the microspheres have a particle size range of 50-400  $\mu\text{m}$ .

27. (New) The administration form as claimed in claim 26, wherein the microspheres are monomodal microspheres.

28. (New) The administration form as claimed in claim 27,  
wherein the microspheres have a particle size range of 50-200  
µm.

29. (New) The administration form as claimed in claim 1,  
wherein the fatty alcohol is selected from the group  
consisting of cetyl alcohol, myristyl alcohol, lauryl alcohol,  
stearyl alcohol and mixtures thereof.

30. (New) The administration form as claimed in claim 2,  
wherein the triglyceride is selected from the group consisting  
of tristearate, tripalmitate, trimyristate and mixtures  
thereof.

31. (New) The administration form as claimed in claim 2,  
wherein the fatty acid ester is cetyl palmitate.

32. (New) The administration form as claimed in claim 1,  
wherein the solid paraffin is paraffinum solidum or ozocerite.

33. (New) The active compound unit as claimed in claim 11,  
wherein the proton pump inhibitor is selected from the group  
consisting of omeprazole, pantoprazole, lansoprazole and

rabeprazole.

34. (New) The active compound unit as claimed in claim 11,  
wherein the proton pump inhibitor is pantoprazole sodium  
sesquihydrate, (-)-pantoprazole sodium sesquihydrate,  
omeprazole magnesium, omeprazole, esomeprazole magnesium or  
esomeprazole.

35. (New) The active compound unit as claimed in claim 11,  
wherein the proton pump inhibitor is pure enantiomer.

36. (New) The active compound unit as claimed in claim 11,  
wherein the proton pump inhibitor is esomeprazole or (-)-  
pantoprazole.

37. (New) The active compound unit as claimed in claim 15,  
wherein the microsphere has a particle size range of 50-500  
µm.

38. (New) The active compound unit as claimed in claim 15,  
wherein the microsphere has a particle size range of 50-400  
µm.

39. (New) The active compound unit as claimed in claim 38,  
wherein the microsphere is a monomodal microsphere.

40. (New) The active compound unit as claimed in claim 38,  
wherein the microsphere has a particle size range of 50-200  
µm.

41. (New) The active compound unit as claimed in claim 11,  
wherein the fatty alcohol is selected from the group  
consisting of cetyl alcohol, myristyl alcohol, lauryl alcohol,  
stearyl alcohol and mixtures thereof.

42. (New) The active compound unit as claimed in claim 12,  
wherein the triglyceride is selected from the group consisting  
of tristearate, tripalmitate, trimyristate and mixtures  
thereof.

43. (New) The active compound unit as claimed in claim 12,  
wherein the fatty acid ester is cetyl palmitate.

44. (New) The active compound unit as claimed in claim 11,  
wherein the solid paraffin is paraffinum solidum or ozocerite.

45. (New) The administration form as claimed in claim 9, wherein the inorganic basic salts are selected from the group consisting of ammonium carbonate and sodium carbonate.

46. (New) The administration form as claimed in claim 9, wherein the amines are selected from the group consisting of meglumine, di- or triethylamine and TRIS (2-amino-2-hydroxymethyl-1,3-propandiol).

47. (New) The administration form as claimed in claim 9, wherein the fatty amine is stearylamine.